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10/722,318	11/25/2003	Tamiko Sadaie	2793	9319

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/722,318

Applicant(s)

SADAIE, TAMIKO

Examiner

Lora E Barnhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7 is/are rejected:
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/25/03, 3/31/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-5 and 7, in the reply filed on 1/6/2005 is acknowledged. Claims 6 and 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The requirement is made FINAL.

Specification

The disclosure is objected to because of the following informalities: It recites numerous scientific names that are incorrectly formatted, for example at p.2, paragraph 2. Scientific (Latin) names of organisms should be italicized or underlined, and the first letter of the genus only should be capitalized, e.g. *Mucor indicus*. The names of higher taxa such as family names and order names should also be italicized, e.g. *Nitrobacter*. In addition, the word "Myxococcus" is misspelled in Table 1. The specification should be reviewed carefully throughout for accuracy of scientific names. Appropriate correction is required.

Claim Objections

Claims 1, 5 and 7 are objected to because of the following informalities: They recite "electron-accepters," which is misspelled. The claims should be amended to recite "electron-acceptors."

Claim 2 is objected to because of the following informalities: It recites numerous scientific names that are incorrectly formatted. Appropriate correction is required as

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directed above for the specification. In addition, line 11 of the claim should be amended to recite "*Methylosinus trichosporium*".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3-5 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The standard for patentability in the area of **living organisms** and biomolecules is whether the claimed matter "is the result of human intervention." See M.P.E.P. § 2105. Independent claims 1, 5 and 7 recite compositions comprising fungi and bacteria, but the manner of production of this composition does not necessarily require the hand of man, as low-oxygen environments as recited exist in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically *Methylosinus trichosporium*. It is noted that an ATCC deposit number is provided for said materials, but the ATCC has no record of any organism's being

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deposited under the number 35070. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials.

The specification does not disclose a repeatable process to obtain the biological materials, and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the biological materials (p.9), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 is drawn to a composition comprising a specific strain of *Mucor indicus* and eight specific bacterial strains, produced by growing together in a low-oxygen environment. The specification further describes this environment as being "domestic sewage" (p.13), and the declaration signed by applicant on 9/30/03 is in Japanese and gives the applicant's citizenship and mailing address as Japanese. It is therefore assumed that the domestic sewage recited in the Examples is also Japanese. A search for the recited strain numbers in the ATCC database, however, shows that none of the claimed strains are native to Japan (reference U). Four are native to the United States (ATCC 23107, ATCC 14909, ATCC 31898 and ATCC 14580), two are native to India (ATCC 49305 and ATCC 700366), and one is native to the Philippines (ATCC 90364). The composition of fungi and their symbiotic bacterial group are disclosed as being produced by culturing Japanese domestic sewage as described on p.13 of the specification. Since none of the claimed strains of fungi or bacteria are present in Japanese domestic sewage (or, indeed, sewage from any single location on Earth), the applicant cannot have been in possession of a process that comprises culturing sewage as disclosed and yields the precise composition of claim 2.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5 and 7 recite growing fungi and their symbiotic bacterial group "in an environment where an oxygen concentration is kept **essentially** at 1ppm or less," which does not clearly define the metes and bounds of the claim. It is not clear whether any conditions other than those claimed are encompassed by the claim. The examiner notes applicant's definition of "essentially" at p.7, paragraph 2 of the specification but asserts that said definition does not precisely limit the claims. Applicant defines "essentially 1ppm or less" to mean "**around** 1ppm including a **minute range** above that limit," a definition which itself is replete with indefinite language. Claims 1, 5 and 7 further recites "carbon sources for a nutrient and electron-acceptors including inorganic salts." It is not clear whether carbon sources are both nutrients and electron-acceptors, or simply as nutrients. Table 1 recites at least one electron-acceptor that comprises carbon (fumarate). Because claims 2-4 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 2 recites fungi and their symbiotic bacterial group "as predominant organisms," which does not precisely define the metes and bounds of the claims. It is not clear which conditions comprise "predominant." Clarification is required.

Claim 4 recites "cellulose substances", which does not precisely define the metes and bounds of the claims. It is not clear how "cellulose substances" are related to or derived from cellulose or, indeed, which substances are included and excluded by the claim. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Higa (1997, U.S. Patent 5,591,634; reference A) in light of Kickuth et al. (1988, U.S. Patent 4,793,929; reference B). The claims are drawn to a composition of fungi and their symbiotic bacterial group produced by growing together in a low-oxygen environment.

U.S. '634 teaches a composition comprising the mold fungi *Aspergillus japonicus*, *Aspergillus oryzae* and *Mucor hiemalis* and the bacteria *Streptomyces albus*, *Streptoverticillium baldaccii*, *Nocardia asteroides*, *Micromonospora chalicea*, *Rhodopseudomonas sphaeroides*, *Rhodospirillum rubrum*, *Chromatium okenii*, *Lactobacillus bulgaricus*, *Propionibacterium freudenreichii*, *Pediococcus halophilus*, *Streptococcus lactis*, and *Streptococcus faecalis* (Example 1). U.S. '634 further teaches that said composition can grow under "closed and airtight conditions" (column 6, lines 8-14) and can subsist on "kitchen waste" for at least 14 days (Example 11).

U.S. '929 demonstrates the conversion of ammonia naturally present in sewage water to nitrate (column 2, line 60-column 3, line 4 and column 10, lines 12-45). With regard to the presence of "cellulose substances" in the environment of claim 4, paper is commonly found in domestic sewage.

Claims 1, 5 and 7 are product-by-process claims; claims 2-4 depend from said claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. *The patentability of a product does not depend on its method of production.* If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, *it is the patentability of the product claimed and not of the recited process steps which must be established.* We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product

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claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '634 (A) taken with U.S. '929 (B) and Miyaji (1971, U.S. Patent 3,607,736; reference C). The claims are drawn to a composition as described above. In some dependent claims, the fungi and bacteria of the composition are specified in a list.

U.S. '634 teaches a composition comprising *Mucor hiemalis* and various bacteria from numerous families, as discussed above. U.S. '736 is cited as evidence that

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addition of nitrate to sewage is well known in the art for facilitating treatment of said sewage (Example 1 and column 1, line 71-column 2, line 11). U.S. '929 is cited as evidence that ammonia naturally present in sewage is naturally converted to nitrate (column 2, line 60-column 3, line 4 and column 10, lines 12-45). With regard to the presence of "cellulose substances" in the environment of claim 4, paper is commonly found in domestic sewage. The bacteria and fungus of U.S. '634 are disclosed as being able to live together in kitchen waste for at least 14 days, as discussed above, but U.S. '634 does not teach the precise composition of claim 2.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' *Mucor* strain differs, and if so to what extent, from the strains discussed in U.S. '634. Accordingly, it has been established that the prior art strain, which has the same genus classification and shares the properties of being able to live in low-oxygen environments and subsisting on domestic waste, demonstrates a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

The language of claim 2 does not exclude the possibility that the claimed composition comprises one or all of the bacteria of Example 1 of U.S. '634. Since said bacteria share the properties with the claimed bacteria of being symbiotic to a *Mucor* fungus, surviving in low-oxygen environments, and subsisting on organic waste, the composition of U.S. '634, Example 1, is sufficiently similar to the claimed composition

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that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known strain or mixture is not disclosed in a reference does not make the known strain patentable. The known strain and mixture possess inherent characteristics which might not be displayed in the tests used the reference. However, the microbe and mixture disclosed in U.S. '634 may be the same microbe and mixture as instantly claimed. Clear evidence that the strains and mixtures of the cited prior art do not possess a critical characteristic that is possessed by the claimed strain, would advance prosecution and might permit allowance of claims to applicants' strain.

A person of ordinary skill in the art would have had a reasonable expectation of success in making a composition of fungi and bacteria as recited in claim 2 because U.S. '634 teaches that such compositions are capable of living together in low-oxygen environments. The skilled artisan would have been motivated to combine bacteria with fungus in the treatment of organic waste for the expected benefit of increasing the efficiency of waste treatment. U.S. '634 teaches that combinations of bacteria, fungi and yeast provide "continuous and efficient degradation of organic waste," with the different species metabolizing different components of the waste with different enzymes and preventing infestation with undesirable Gram-positive bacteria. U.S. '634 also teaches that "any microorganism can be used" for degradation of organic waste (column 3, lines 39-65). Additionally, the skilled artisan would have had a reasonable expectation of success in adding nitrate to the composition because U.S. '736 and U.S. '929 teach

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compositions comprising added nitrate and nitrate converted from natural ammonia, respectively, that are useful in the purification of sewage. Because most domestic sewage comprises paper, the person of ordinary skill in the art would have had a reasonable expectation of success in adding cellulose substances to the composition.

It would therefore have been obvious to a person of ordinary skill in the art to combine fungus and bacteria into a composition for treating waste because said combinations are disclosed by U.S. '634 as being efficient and effective solutions to organic waste disposal problems. Additionally, U.S. '736 and U.S. '929 teach compositions comprising nitrate as being useful in aiding sewage treatment, and paper is a common component of sewage.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart


IRENE MARX
PRIMARY EXAMINER